

### III. New Claims 21-31

Original claims 1-20 are cancelled and new claims 21-31 are added to this application by this preliminary amendment. All of the new claims 21-31 are supported by the original specification as set forth below:

Claim 21 is directed to a method for treating a muscle spasm using botulinum toxin type B, and claim 21 is supported by at least Examples 1, 2, 3, 4, 6, 7, 8, 9, 9 and 10 of the original specification. The Examples set forth use of botulinum toxin type B to treat broad and diverse muscle spasms. Examples 6, 7, 8, 9 and 9 (second example 9) are entitled "The Use of Botulinum Toxin Types A-G in the Treatment of Muscle Spasms...".

The Examples set forth examples of use of botulinum toxin type B toxin to treat tardive dyskinesia muscle spasms (Example 1), spasmodic torticollis muscle spasms (Example 2(a)), essential tremor muscle spasms (Example 3), spasmodic dysphonia muscle spasms (Example 4), smooth sphincter muscle spasms (Example 6), Temporal Mandibular Joint muscle spasms (Example 7), sports injury muscle spasms (Example 8), smooth muscle gastrointestinal muscle spasm (Example 9), muscle spasms secondary to trauma (Example 9), and throat muscle spasms (Example 10).

Claim 22 is supported by at least page 7, lines 11-15 of the specification.

Claim 23 is supported by at least Examples 6, 7, 8 and 9 on pages 17-18 of the specification.

Claim 24 is supported by at least page 8, lines 24-26 of the specification and Example 2(a) on page 11, lines 10-15 of the specification.

Claim 25 is supported by at least page 1, line 24 of the specification.

Claim 26 is supported by at least page 1, line 23 of the specification.

Claim 27 incorporates the limitations of claims 21, 22 and 23.

Claim 28 is supported by at least page 1, line 24 of the specification.

Claim 29 is supported by at least page 1, line 23 of the specification.

Claim 30 incorporates the limitations of 21, 22, 23 and 25.

Claim 31 incorporates the limitations of claims 21, 22 , 23 and 26.

#### IV. Claims 21-31 are in Condition for Allowance

Enclosed is a copy of the February 8, 2001 declaration of Mitchell Brin, which declaration was submitted in co-pending application serial number 09/490,756 with applicants response dated February 16, 2001 in co-pending application serial number 09/490,756.

Paragraph 6 of the Brin declaration states: "As of the April 25, 1991 date of the Jankovic reference it was completely unknown as to whether or not botulinum toxin type B would have any therapeutic efficacy in humans. Indeed, as far as I am aware, the first reported use of type B botulinum toxin in humans did not occur until 1995."

Additionally, paragraph 8 of the Brin declaration states: "In my opinion, prior to December 28, 1993, it would have been foolhardy and dangerous to use botulinum toxin type B to treat patients with dystonia, such as cervical dystonia,

in light of the complete lack of clinical experience with the type B toxin as of that date."

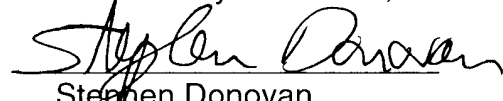
The Brin declaration is submitted herein as evidence that the claims in this application are in condition for allowance. In other words, since there had been no use of botulinum toxin type B to treat any disease condition prior to the effective filing date of the present application (December 23<sup>8</sup>, 1993) and based upon the additional evidence presented by the Brin declaration, the present claims 21-31 being directed to use of a botulinum toxin type B to treat a muscle spasm are free of the art and in condition for allowance.

V. Conclusion

Examination and allowance of claims 21-31 is requested.

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Respectfully Submitted,

  
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I hereby certify that the Transmittal Letter, the divisional patent application, preliminary amendment, and the documents referred to as enclosed therein are being deposited with the United States Postal Service on this date July 11, 2001

in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EL385557492US addressed to Box Patent Application, Assistant Commissioner for Patents, Washington, D.C. 20231

Susan Bartholomew  
Name of person mailing paper

Date: July 11, 2001

  
Signature of person mailing paper